

Clinical Pharmacology Memo	
NDA	200678 Supplement 028
Submission Date:	12/12/2023
PDUFA Date:	10/11/2024
Brand Name:	Kombiglyze XR
Generic Name:	Saxagliptin and metformin HCL
Sponsor:	AstraZeneca
Dosing regimen:	2.5 mg or 5 mg saxagliptin/500 mg or 1000 mg metformin HCl extended release. Do not exceed a daily dose of 5 mg saxagliptin/1000 mg metformin HCl extended release.
Dosage Form	Extended-release tablets
Proposed Indication:	adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
OCP Reviewer:	Dong Guo, PhD
OCP Team Leader:	Edwin Chiu Yuen Chow, PhD
OCP Division:	Division of Cardiometabolic and Endocrine Pharmacology (DCEP)
OND Division:	Division of Diabetes, Lipid Disorders, and Obesity (DDLO)

The supplement NDA (sNDA) submission is an efficacy supplement with data from the pediatric study (D1680c00019). The Applicant did not conduct additional PK/PD study in pediatric patients. The Applicant is not seeking a pediatric indication for saxagliptin, as efficacy was not demonstrated in the 10-17 years old pediatric subjects with type 2 diabetes mellitus (T2DM). At Week 26, the adjusted mean change from baseline (SE) in HbA1c was 0.06% (0.198%) in the saxagliptin group and 0.50% (0.202%) in the placebo group, resulting in a difference of -0.44% (95% CI -0.93, 0.05; p =0.078). The label related to clinical pharmacology was not substantially changed. Therefore, a detailed clinical pharmacology review was not conducted.

The clinical pharmacology team considers PMR 3199-1 to be fulfilled.

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/s/

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06/17/2024 11:30:26 AM

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06/21/2024 02:42:27 AM

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